

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number WA4-01				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2021 Base Option Period Number 4			Title of Work Assignment/SF Site Name Lead-Based Paint Program				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW Taks II. III. and IV.					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2020 To 06/12/2021				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div>										
Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
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Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:			LOE:					
06/13/2016 To 06/12/2021										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee			LOE:			
Cumulative Approved:				Cost/Fee			LOE:			
Work Assignment Manager Name Darlene Leonard							Branch/Mail Code:			
<div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> (Signature) (Date)							Phone Number: 202-566-0516			
							FAX Number:			
Project Officer Name Sheila Brown							Branch/Mail Code:			
<div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> (Signature) (Date)							Phone Number: 202-564-4651			
							FAX Number:			
Other Agency Official Name							Branch/Mail Code:			
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<div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> (Signature) (Date)							Phone Number: 513-487-2155			
							FAX Number:			

STATEMENT OF WORK

Contract Number: EP-W-16-017

Work Assignment Number: 4-01

Title: Support for the Lead-Based Paint Program and Other National Program Chemicals

I. Purpose and Background

The purpose of this Work Assignment is to provide technical support of the implementation of the Renovation, Repair and Painting Program (RRP) as well as all other aspects of the Lead-Based Paint Program and of other priority existing chemicals. This is a continuation of work to extend the performance period that began under the previous work assignment, Work Assignment 3-01 of contract EP-W-16-017. No work shall be duplicated.

Title IV of the Residential Lead-Based Paint Poisoning Prevention Act requires EPA to undertake various actions to reduce the incidence of lead poisoning. These actions include technical studies to support rule making, outreach to the regulated community, outreach to the public and support of the regulatory functions.

Title IV of the Residential Lead-Based Paint Poisoning Prevention Act requires EPA to undertake various actions to reduce the incidence of lead poisoning. Specifically Section 405 (a) says “ The Administrator, in cooperation with other appropriate Federal departments and agencies, shall conduct a comprehensive program to promote safe, effective, and affordable monitoring, detection and abatement of lead-based paint and other lead exposure hazards” Section 405 (d) says “the Administrator in conjunction with the Secretary of Health and Human Services...and in conjunction with the Secretary of Housing and Urban development, shall sponsor public education and outreach activities to increase public awareness...”

Throughout the year, EPA provides lead awareness and educational outreach to various audiences. In addition, EPA partners with the Centers for Disease Control and Prevention (CDC) and the Department of Housing and Urban Development (HUD) to collaborate on a theme and develop posters and flyers and other education and awareness tools and events specifically designed to observe National Lead Poisoning Prevention Week (NLPPW). EPA also promotes the Lead Week of Action, a lead awareness effort on an international scale.

Additionally, technical support is needed for other work in the National Program Chemicals Division (NPCD). NPCD is responsible existing chemicals that are ready for hazard management. Currently those chemicals include lead, mercury, formaldehyde, and asbestos. NPCD also has new responsibilities related to manufacturer requests for risk evaluations and for several existing chemicals identified as “high priority” for risk evaluation.

II. Scope of Work

Task 1 - Storage of Records

The Contractor shall arrange for storage facilities for RRP paper records. These are active records and must be available in the Washington, D.C. metropolitan area. The records must be stored in a secure area and be available for EPA personnel within 24 hours. When directed by the Work Assignment Contracting Officer Representative (WACOR), the Contractor shall arrange for pickup of additional records from within another location in the Washington, D.C. area. The Contractor shall maintain the existing filing methodology and file any new records accordingly.

Task 2 - Cleaning Verification Cards

When directed by the COR, the Contractor shall provide Cleaning Verification Cards that meet the quality control standards previously developed. The cards shall be shipped to the National Lead Information Center in Rochester, NY. It is anticipated that the cards will be produced in batches of 150,000. Assume one batch will be required.

Task 3 - Support of the Outreach Efforts at Conferences and Trade Shows

When directed by the EPA Work Assignment Contracting Officer Representative (WACOR), the Contractor shall purchase meeting rooms and exhibit space at conferences and trade shows, ship and staff the EPA-provided booth, if needed. These services include shipping the EPA booth to venues and returning it to a location designated by the COR. Also included in this task is paying for incidental fees such as conference venue drapes, delivery charges, etc.

Task 4 - Technical Studies

When directed by the WACOR, the Contractor shall produce studies on Lead-Based Paint issues. These studies are anticipated to be of short duration, typically less than 30 days. The exact nature of the study and due date will be contained in the technical direction. Anticipated topics are work practices on Public and Commercial Buildings and other rules in development or under consideration, including analyses on the Lead Dust Study and clearance levels.

Task 5 - Revisions to Documents

When directed by the WACOR, the Contractor shall provide technical support for general lead, mercury and PCBs, and other national program chemicals outreach, including revising and finalizing EPA pamphlets, poster, banners, flyers for web posting or printing, and developing outreach presentations. The Contractor shall produce both an English and Spanish versions of the documents, when needed and directed by the WACOR.

Task 6 - Lead Outreach Support

When directed by the COR, the Contractor shall provide support for outreach effort to the regulated community on the Renovation, Repair and Painting Rule and/or other regulations or topics related to lead. The Contractor shall help to identify target audiences. This includes finalizing EPA pamphlets, poster, banners, flyers for web posting or printing, developing outreach presentations, translation of existing EPA documents into additional languages, and outreach support to Native American tribes (and other vulnerable communities), the purchase of mailing lists, USB drives and CDs, minimal printing and binding of materials (hard copy and onto USB drives and/or CDs) (within the allowable limits of the contract) to disseminate the materials. The

Contractor shall develop posters, flyers, a resource package, web banners and other education and awareness tools specifically designed to observe National Lead Poisoning Prevention Week (NLPPW) and International Lead Poisoning Prevention Week (ILPPW).

The Contractor shall provide support for activities that encourage non-certified RRP firms to become certified or to renew their RRP firm certification in up to 4 select cities as identified by the EPA COR. Using housing inventory from the U.S. Census 5-year American Community Survey (ACS) 2017 inventory of pre-1979 housing, coupled with metrics on the number of children under 6 years old from the Census data tracking within the geographical areas, and if available, refugee population, determine which cities should be targeted to participate in the project. The activities shall include, but not be limited to, reserving venues to arrange for informational events on RRP for renovators, coordinating with building code officials, hardware stores and national trade associations to encourage those seeking renovation permits to become informed about the RRP rule, developing graphic designs for posters and web banners, radio and TV ads to announce meetings or events on RRP. The Contractor shall work with the EPA WACOR to determine when and what type of outreach event will be held in each specific city.

Task 7 - National Program Chemicals Support

When directed by the WACOR, the Contractor shall provide support to other national program chemicals including but not limited to mercury, formaldehyde, and asbestos. The Contractor shall provide technical support for regulatory and non-regulatory activities involving risk reduction and hazard management of national program chemicals. Technical support includes but is not limited to technical studies and investigation supporting risk evaluation and rulemaking, outreach to the regulated community, outreach to the public and support of regulatory and non-regulatory functions. The Contractor shall provide technical support related to manufacturer requests for risk evaluations and for several existing chemicals identified as “high priority” for risk evaluation under TSCA as directed by the EPA WACOR. This support will involve supporting development of risk evaluation scope documents including researching regulatory histories, identifying conditions of use, interfacing with manufacturers, users and other stakeholders, and developing supporting documents.

III. Deliverables

Task	Deliverable	Due Date
Tasks 1 - 3	A letter report providing statistics on the activity for the contract period shall be provided.	Included in the monthly progress report.
Task 4	Technical Studies: <ul style="list-style-type: none"> • Draft and final report • QA/QC plan 	As directed by Technical Direction
Task 5	Document Revisions: Electronic and/or CDs of the professional print files of the documents ready for printing and/or posting (508-compliant) onto the EPA webpage.	As directed by Technical Direction
Task 6	Lead Outreach Support: A letter report detailing the activities performed. Electronic (and/or USB or CDs) of the professional print files of any documents prepared for printing and/or posting (508-compliant) onto the EPA	As directed by Technical Direction

	webpage and distribution.*	
Task 7	National Program Chemicals Support: <ul style="list-style-type: none"> • Draft and final report • QA/QC plan 	As directed by Technical Direction

*For the RRP Outreach Program portion of the task, the Contractor shall provide a summary letter report of providing statistics each activity. The letter shall summarize the work completed and shall include what outreach activities occurred and the number of people reached. In addition, the report will include:

- A description of ads printed for each outreach session in each of the cities.
- A description of the actual outreach event held in each of the cities, including the name, location of the venue, date, and time.
- A description of the number of firms contacted and sources used to develop list of renovation firms to contact.
- An analysis of which outreach messages and delivery mechanism were most and least effective.

IV. Period of Performance:

June 13, 2020 through June 12, 2021.

V. EPA Contacts:

A. Work Assignment Contracting Officer Representative:

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Program Assessment and Outreach Branch (7404T)
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B. Alternate Work Assignment Contracting Officer Representative:

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Shannon.julie@epa.gov

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number WA4-03				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2021 Base Option Period Number 4			Title of Work Assignment/SF Site Name Technical Support for the PCB				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW 3					
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Total:										
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Contractor WP Dated: Cost/Fee LOE:										
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Work Assignment Manager Name Sheila Brown <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>						Branch/Mail Code:				
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Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>						Branch/Mail Code:				
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Contracting Official Name Erin M. Ridder <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>						Branch/Mail Code:				
						Phone Number: 513-487-2155				
						FAX Number:				

STATEMENT OF WORK

CONTRACT NUMBER: EP-W-16-017

WORK ASSIGNMENT: 4-03

TITLE: Technical Support for the PCB Program

BACKGROUND:

The Toxic Substance Control Act (TSCA) of 1976 requires EPA to develop rules to regulate the manufacture, processing, distribution in commerce, use, or disposal of chemical substances. Section 6(e) of the Act specifically names polychlorinated biphenyls (PCBs), requiring rules to specify methods for the disposal of PCBs. Regulations promulgated in Subpart D of 40 CFR 761 authorize EPA to issue PCB disposal approvals, valid nationwide, to mobile disposal facilities and fixed facilities as well as issue PCB alternative decontamination approvals. TSCA regulations delegate signatory authority to the Assistant Administrator of the Office of Solid Waste and Emergency Response (OSWER) for permits issued by EPA. In FY 2008, EPA transferred the administration and implementation of the Toxic Substances Control Act's (TSCA) Polychlorinated Biphenyl (PCB) Cleanup and Disposal Program from the Office of Prevention, Pesticides and Toxic Substances (OPPTS) to the Office of Solid Waste and Emergency Response (OSWER), now known as the Office of Land and Emergency Management (OLEM).

Individuals seeking approvals to dispose of PCBs or decontaminate PCB-contaminated materials must submit a permit application and a demonstration plan for EPA review. EPA reviews the permit application for completeness. The application must include the demonstration plan indicating a demonstration can be performed safely with a good probability of success. Once the application review is complete, EPA requires the company to demonstrate the operation of its technology under reasonable worst-case operating conditions. EPA issues an approval to operate the alternative disposal or decontamination technology once the company has demonstrated their PCB disposal or decontamination process is effective, the technology is capable of processing PCB material without frequent breakdowns and does not present unreasonable risks to health and the environment.

PCB disposal technologies are typically classed into three categories, (a) incineration, (b) thermal alternative technology, and (c) non-thermal alternative technology. Alternative technologies include surface and aqueous media decontamination processes. The alternative disposal technology is required to be demonstrated in the presence of EPA evaluators. During the demonstration, EPA collects samples of materials before and after treatment to confirm the PCBs were destroyed. Upon confirmation of PCB destruction, EPA will issue an approval for the technology. This work assignment is a follow-on to WA 3-03 and addresses 7 on-going tasks in support of the PCB program.

PURPOSE:

Anyone wanting to dispose of PCBs are required to use approved methods and obtain an approval. Several methods for disposal and decontamination are listed in 40 CFR §761, however, alternative technologies for disposal and decontamination may be used if approval is granted by the EPA. Persons can apply to the EPA for approval of PCB disposal by non-thermal alternative methods

(§761.60(e)), alternative decontamination procedures (§761.79(h)), thermal alternative methods (§761.60(e)), and incineration (§761.70). EPA must confirm the PCB Disposal and decontamination technologies demonstrated by permit applicants comply with EPA requirements. To accomplish this, EPA will require contractor support.

SCOPE OF WORK: TASKS

TASK 1: Task Management

- The Contractor shall prepare and submit a work plan in accordance with the terms and conditions of the Base contract. Work under this task shall include participating in project update meetings/teleconferences, preparing the monthly progress reports and other task management.
- Quality Assurance Project Plans (QAPP) are required under the Agency's Quality Assurance Policy CIO-2105, formerly EPA Order 5360.1A2 and implementing guidance CIO-2105-P-01-0. In addition to abiding by its own Quality Management Plan that has been approved by EPA, all tasks that involve the generation, collection, analysis and use of environmental data shall have an approved QAPP prior to the commencement of the work.
- All major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) shall include a discussion of the QA/QC activities performed to support the deliverable. For example, a Technical Support Document or Study Report shall include a clear discussion of the quality management strategies that were employed to control and document the quality of data generated and used.
- The QAPP does not have to be submitted at the same time as the Technical and Financial Work Plan unless the environmental data activities covered under the QAPP are to begin immediately. In many cases, planning for how to perform the work is needed before the QAPP can be prepared and submitted to EPA for approval. For example, once Task 2 is funded, the QAPP will be submitted; however, no work involving the generation, collection, analysis and use of environmental data can begin until an EPA approved QAPP is in place.

NOTE: The tasks below represent all the possible items that shall be required by EPA to support the PCB cleanup and disposal program. Written technical direction will be provided by the WACOR to specify the items and quantities needed for each task.

TASK 2: Sample Collection and Analysis

- A. EPA will observe on-site the PCB Disposal or Decontamination Demonstrations and will collect samples and transfer the samples to the Contractor. The Contractor shall analyze the samples appropriately, as outlined below.
1. For analysis of polychlorinated biphenyls (PCBs), the Contractor shall analyze samples for classes of PCB compounds called Aroclor. These compounds include but are not limited to the following:

Aroclor 1242	Aroclor 1260	Aroclor 1016
Aroclor 1254	Aroclor 1264	
 2. For analysis of PCBs, the Contractor shall provide analytical instrument capability and methodologies to analyze and to identify the 209 congeners of polychlorinated biphenyls.

3. For analysis of PCBs, the Contractor shall provide analytical instrument capability and methodologies to analyze and to identify PCBs, separating and quantitating the identified PCBs in homologs from mono- to deca-chlorinated biphenyls. The analytical standard to be used shall be the Dry Color Manufacturer Association (DCMA) standard or equivalent.
 4. The Contractor shall transmit analytical results of the demonstration samples to EPA in three stages. First, the raw data will be submitted by telephone or email as directed by the WACOR. These results will assist EPA in determining the efficacy of the new disposal or decontamination technologies. Second, the Contractor shall prepare a draft digital report. Third, after receiving comments from the WACOR, the Contractor shall then prepare the final analytical results which incorporate the WACOR's comments.
 5. The Contractor shall analyze for other pollutants of interest as directed by the WACOR. For example, PCBs in the U.S. is in short supply. The possibility exists that surrogates for PCBs may necessarily be used during PCB Disposal or Decontamination Demonstration. Should surrogates be used, the Contractor shall analyze samples for the surrogates. An example of a surrogate is trichlorobenzene.
- B. Sample Media. The Contractor shall implement analytical methods suitable to the medium of interest. Examples of media include crankcase oil; mineral oil; solvents such as ethylene glycol; soils such as clay, sediment or sand; fly ash; and clinkers.
- C. Sampling Kit.
1. The Contractor shall provide sampling kits (as described in **Task 4**) for each demonstration suitable for the collection of samples of various media, but not limited to bulk solids such as soil; and bulk liquids such as fuel oil, solvents and water.
 2. The Contractor shall provide a sampling kit suitable for the collection and analysis of samples from porous surfaces (concrete, paint) and non-porous surfaces (metal).
- D. For thermal technologies including incineration, the Contractor may be requested by the WACOR to observe the collection of samples from various process streams and obtain split samples for analysis by the Contractor.
- E. The Contractor shall provide personnel with appropriate experience and appropriate certificates to take the samples for any of the technologies and media.
- F. The Contractor shall submit a preliminary analysis to the WACOR for review and comment. Upon receipt of the comments the Contractor shall incorporate the comments into the final report.

TASK 3: PCB Disposal and Decontamination Demonstration Requiring Review of Sampling Protocols

- A. For thermal technologies including incineration, the Contractor may be requested by the WACOR to review the applicant's demonstration trial burn plan, to determine/plan the work schedule. Contractor shall already be familiar with the process and equipment, from previous work with identical incinerator equipment.
- B. For thermal technologies including incineration, the Contractor shall determine if the applicants' stack emission sampling protocols to be used during the trial burn comply with EPA standards.

TASK 4: Sampling Kit and Performance Evaluation (PE) Samples

The Contractor shall provide, at the direction of the WACOR, a sampling kit for EPA PCB Disposal or Decontamination technology evaluators. Sampling items are to be shipped in a cooler ranging in size from one (1) gallon to ten (10) gallons, as appropriate. Packing material shall be provided and used as appropriate to minimize breakage of items.

At minimum, the following items shall be provided in the shipping cooler:

- A. Traceability Log Forms (3 sheets minimum)
- B. Quadruplicated bar codes in self-adhering format (3 sheets - 15 codes minimum per sheet). Traceability forms must accommodate bar codes and sample description.
- C. Labels for sample containers to identify samples.
- D. Disposable gloves (12 pairs minimum)
- E. Wide mouth 100 ml. sampling jars, or 40 ml. vials "VOC" sampling type, or a mixture of jars and vials as specified by WACOR.
- F. Spatulas, two medium size, metal
- G. One fine tip marker, waterproof
- H. Two writing pens, ball point or fine felt tip
- I. "Blue ice" or chemical ice pack for sample preservation
- J. Evidence tape, 2 feet in length
- K. Shipping bill or air bill prepared for shipping samples to Contractor on overnight basis
- L. "Zip locking" plastic bag to protect documents
- M. Extra sampling containers in case of breakage or process anomaly
- N. Paper towels, e.g. "Kimwipes"

Optional items below, which are required at times, specified by the WACOR, for specific projects:

- O. One-liter jars for aqueous samples, quantity to be specified.
- P. Wipe Sampling Kit:
 - 1. Folded cotton gauze pad (e.g. 4"x4"), inserted in 100 ml wide mouth jar
 - 2. Gauze pad saturated with solvent (e.g. hexane)
 - 3. Template for wiping 100-centimeter square area or as specified
 - 4. Template disposal or reusable, as specified
 - 5. Quantity to be specified by WACOR
 - 6. Solvent to be specified by WACOR
- Q. Spoon or other instruments for sampling

Blind PE samples shall be prepared to evaluate laboratory(s) designated by applicants to analyze samples for the demonstration or for commercial operations. The PE sample(s) may be prepared using various media such as sand, oil (e.g., mineral oil dielectric fluid, MODEF), or water and at various concentrations as directed by the COR (e.g., Aroclor 1260 in MODEF, 10 g in flame sealed ampules; one between 15,000 – 18,000 ppm, one between 5 -10 ppm, and one between 0.5 - 2 ppm).

TASK 5: Compiling Annual PCB Reports

At the direction of the WACOR, the Contractor shall:

- 1. Go through 2019 annual reports (paper or electronic) that are provided by the WACOR and enter the facilities' data into the Excel spreadsheet file provided by the WACOR. The data to be entered will include the data described in the background section above.

2. In a document titled “PCB Annual Report Data Issues,” provide to the WACOR a list of any missing data from any facilities, any facilities’ whose annual reports the contractor was not able to decipher, and any facilities that reported data in previous years, but did not submit reports for subsequent years.
3. Update any graphs that are in the Excel file that the WACOR provides with the new data entered.
4. If requested by the WACOR, follow up with EPA Regional PCB staff or facilities to track down missing, incorrect, or illegible annual reports and make the additions or corrections to the excel spreadsheet and graphs.

TASK 6: PCB Database Entry

Several Regions have either an *Access* database or *Excel* spreadsheet containing their PCB notifications and PCB approvals data. Since EPA is moving to a national PCB database in *RCRAInfo*, there is a need to re-enter all the data from the Regional databases/spreadsheets into *RCRAInfo*. In particular, Region 1’s database contains 757 entries and about 20 fields that are common to both databases. This task will have the Contractor perform the data entry from the Regional databases/spreadsheets into *RCRAInfo*, beginning with the Region 1 database.

The Contractor shall enter as much of the PCB data from the Regional databases/spreadsheets into *RCRAInfo*, within the existing funding limits. The Contractor shall continue entering data from the Region 1 database as well as other Regional database/spreadsheets as they become available. Contractor shall enter the data manually (i.e., typing) and perform a data entry quality assurance check (i.e., every field entered for every site will be double checked for correctness by a separate individual).

TASK 7: Potential Regulatory Changes

The Contractor shall provide assistance to update the PCB Regulations to allow for additional extraction and analytical methods and provide other amendments which clarify the regulations. SW-846 methods for PCB extraction which are not allowed for under the 40 CFR Part 761 regulations, such as EPA Method 3541 (or Automated Soxhlet Extraction), should be compared to the existing method in the PCB Regulations – EPA Method 3540C (or Manual Soxhlet Extraction), to demonstrate equivalent or better extraction efficiencies from the newer method.

Data collection and analysis may be needed to justify a potential regulatory change for the allowance of alternate extraction methods. Only when directed, the Contractor shall assist EPA with:

- Compiling reports (e.g., analytical data report, QA/QC summary report, comparison study report);
- Maintaining records and materials generated during the data collection and analysis;
- Reviewing and responding to documents (e.g. ICR, response to comments, OMB review); and
- Collecting materials (e.g., references, the analytical data and QA/QC summary report, the comparison study report, the statistical analysis report, written articles or publications) that support the regulatory change.

DELIVERABLES

Deliverable	Schedule
Task 1: Task Management	Work Plan shall be submitted within 30 days of issuance of Work Assignment issuance for review and acceptance.
Task 2: Sample Collection and Analysis	<ul style="list-style-type: none"> • Draft results shall be provided within 2 weeks of receipt of samples. • Draft report of the chemical analysis shall be provided within 3 weeks of the receipt of the samples. • Final report shall be provided within 30 days of the WACOR's comments on the draft report.
Task 3: PCB Disposal and Decontamination Demonstration Requiring Review of Sampling Protocols	Review and submit a summary report of the demonstration plan within 20 days of receiving copy of the permit applicant demonstration plan.
Task 4: Sampling Kit and Performance Evaluation (PE) Samples	Ship sampling kit and/or performance evaluation samples to the demonstration site within 3 days of written request from the WACOR.
Task 5: Compiling Annual PCB Reports	<ul style="list-style-type: none"> • The COR will send the necessary reports (~50) to the Contractor on or around July 30th • The Contractor shall update and finalize the excel file by August 30th. An extension may be granted by the WACOR if the deadline cannot be met.
Task 6: PCB Database Entry	Data shall be entered into RCRAInfo within 10 days of receiving databases from the Regions.
Task 7: Potential Regulatory Changes	<ul style="list-style-type: none"> • Review and submit edits and comments within 2 weeks of receiving draft document pertaining to the proposed regulatory change. • Other tasks will be performed as directed by EPA WACOR.

PERIOD OF PERFORMANCE: June 12, 2020 through June 13, 2021.

EPA CONTACTS:

Work Assignment Contracting Officer Representative

Jenny McLeod
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Washington, DC 20460
Phone: (703) 308-8459

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Room S-6313
Arlington, VA 22202

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number WA4-07				
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Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:			LOE:					
06/13/2016 To 06/12/2021										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:					Cost/Fee			LOE:		
Cumulative Approved:					Cost/Fee			LOE:		
Work Assignment Manager Name Tony Mcdonald							Branch/Mail Code:			
_____ (Signature) (Date)							Phone Number: 919-541-1476			
							FAX Number:			
Project Officer Name Sheila Brown							Branch/Mail Code:			
_____ (Signature) (Date)							Phone Number: 202-564-4651			
							FAX Number:			
Other Agency Official Name							Branch/Mail Code:			
_____ (Signature) (Date)							Phone Number:			
							FAX Number:			
Contracting Official Name Erin M. Ridder							Branch/Mail Code:			
_____ (Signature) (Date)							Phone Number: 513-487-2155			
							FAX Number:			

PERFORMANCE WORK STATEMENT

Contract: EP-W-16-017

Work Assignment: 4-07

TITLE: Predictive Mathematical Modeling of Water Contaminant Mixture Data

PURPOSE

The purpose of this Work Assignment is to provide statistical expertise and modeling in support of: a) research designed to understand the potential human health risk(s) associated with exposure to contaminants in water, such as disinfection byproducts (DBPs) and emerging contaminants including but not limited to transformation byproducts and anthropogenic chemicals; b) research designed to improve our ability to create appropriate groups of chemicals for experimental evaluation or risk assessment; and, c) research designed to improve our ability to predict accurately the joint toxic action of chemical mixtures and to determine those components responsible for the majority of the toxicity of the mixture. EPA is conducting this research program under the Safe and Sustainable Water Research (SSWR) National Research Program of the U.S. EPA. Specifically, this Work Assignment is for statistical effort to: review manuscripts intended for peer-reviewed journal publication for technical soundness and accuracy of described methods and method results based on analyses conducted either during the current work assignment period or previously by Battelle; extend the development and examination of approaches to discern the contributions of individual chemicals and chemical groups to the toxicity of a chemical mixture; conduct statistical analyses to examine the hypothesis that the toxicity of a group of chemicals can be predicted based on knowledge of the dose-response curves of the chemicals contained in the mixture; to develop, where needed, novel approaches, methods and analyses for grouping chemicals; to conduct research to enhance understanding of the joint toxic actions of groups of chemicals; and, to provide expert consultation and advice in interpretation of results of analyses of chemical mixtures and groups.

BACKGROUND

While the need for toxicological research with both defined and complex mixtures of DBPs and other chemical contaminants of water is well known, the lack of broadly-recognized appropriate statistical methods both to design appropriate experiments and the lack of accepted methods to determine when the effect of defined mixtures of chemicals deviates from that expected under an assumption of dose additivity, has hindered the ability to develop data needed by EPA to evaluate the potential human health risk that might be associated with exposure to the low levels of the groups of chemicals detected in source waters and the corresponding drinking waters and those chemical groups formed or transformed during disinfection of water (DBPs, including transformation DBPs).

Under the Safe and Sustainable Water National Research Program (SSWR), EPA is conducting a series of studies to understand the toxicity of groups of water contaminants, including Candidate Contaminant List Chemicals, DBPs and transformation DBPs. DBPs and transformation DBPs are chemicals formed or transformed during the disinfection of drinking water. DBPs have been associated with adverse health effects through epidemiological and toxicologic studies. Candidate

contaminant list (CCL) chemicals and chemicals of emerging concern (CECs) are of interest, both individually and as groups. Studies at EPA are addressing different source waters and source water characteristics, different drinking waters (CCL and DBP focus) and wastewater treatments (CCL, DBP, CEC focus), with regard to the contaminants present, their concentrations and toxicity, the DBPs formed and their concentrations, and the relative toxic potency of mixture of these chemical contaminants. Understanding those contaminants and contaminant groups that pose the greatest risks to human health will allow risk management and remediation efforts to focus on those that provide the greatest reduction in risk. Integrating toxicological assessments into risk remediation and reduction research provides the opportunity for remediation efforts to focus on those treatments/remedial activities that are most effective at reducing risk.

Predictive models for estimating the effects of contaminants groups will be used, or developed/ revised where necessary and then used, that have the ability to forecast the effects of contaminant groups from single chemical data, creating models that are predictive even when mixture composition changes (fewer chemicals in the mixture, more chemicals in the mixture, the mixing ratio changes as the mixture moves downstream or through the water system). Goals of this program include: development of flexible and accurate predictive models for estimation of the toxicity of contaminant groups that allow for addition and deletion of contaminants and varied specification of chemical concentrations (to enhance usefulness across a spectrum of situations); an improved ability to determine those components responsible for the majority of the toxicity of the mixture; improved understanding of the potential human health risk(s) associated with exposure to environmentally realistic mixtures of contaminants in water; and, the ability to create appropriate groups of chemicals for experimental evaluation or risk assessment.

QA/QC elements consistent with the work requested will be observed during the conduct of this work assignment. These include: 1) before conducting analyses the contractor shall provide the EPA with a written QAPP, EPA QA ID of L-HEEAD-0032700-QP-1 for EPA QA approval as described in Task 1. 2) summary statistics of the data that are being planned for analysis, consisting of sample means, sample standard deviations and sample size for each dose group; 3) potential data quality issues will be presented to EPA as they are identified and prior to proceeding further with analysis; 4) resolution of data quality issues will be documented and approved by EPA before proceeding with analyses. The final report shall include a detailed description of all methods used and the results of analyses conducted, including confidence intervals, statistical significance, multiple comparisons (as appropriate). For any and all final data analyses conducted, the final program(s) used to analyze the data and the summary statistics of the data generated from the final program shall be provided to EPA with the summary statistics consisting of sample means, sample standard deviations and sample size for each dose group.

SCOPE OF WORK

The EPA Work Assignment Contracting Officer Representative (WACOR) will identify the specific deliverables, corresponding delivery dates, and provide additional technical clarification/ directives regarding the tasks of the work assignment listed below through technical directives. Each initial deliverable shall be provided to the WACOR in draft form for review and comment. The contractor shall incorporate procedures to ensure that these drafts completely document the

methodologies; use appropriate assumptions; are accurate, complete, and as specified in the work assignment or technical direction before providing them to the EPA. The contractor shall incorporate EPA review comments into revisions of the drafts. All drafts and final reports shall be approved by the WACOR.

TASKS

Task 1: Prepare and Implement QAPP

All work conducted under this WA shall be performed pursuant to an EPA approved Quality Assurance Project Plan (QAPP) developed by the Contractor and approved by the WACOR, EPA Principal Investigator, and QA Manager. The QAPP with QA Track ID: L-HEEAD-0032700-QP-1, outlines the approach and measures the Contractor shall implement to ensure a high standard of quality in the deliverables. The QAPP shall be in conformance with EPA's Requirements for Quality Assurance Project Plans (EPA QA/R-5). The contractor shall not initiate any research until the EPA approves the QAPP and provides a signed copy. **A QAPP template that covers existing animal data and analysis is included in Attachment 1 of this work assignment.**

Note: The EPA project lead will be responsible for providing the following sections of the QAPP: A9.2, B1, B2, and B3. The contractor is not responsible for content in these sections.

SubTask 1.A: Draft QAPP

The Contractor shall provide the draft QAPP to the EPA WACOR for review.

SubTask 1.B: Final QAPP

The Contractor shall address comments on Deliverable 1.1 and submit the final QAPP document to the EPA WACOR.

Task 2. Workplan and Monthly Progress Report

- A. The Contractor shall prepare a work plan describing tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and, proposed staff names, hours and project roles.
- B. The Contractor shall provide a Table in the Monthly Progress Report that includes a cost summary, the hours allocated, the hours used this month and the cumulative hours used. The table shall also include the EPA, the contractor lead staff, the work assignment number, title and the date.

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours		
					Allocated	Used this month	Cum used

Through technical direction, the WACOR will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

Task 3. Review of Manuscripts

The Contractor shall contribute to the authorship of manuscripts and reports and provide expert review of manuscripts prepared by the EPA for peer-reviewed publication, focusing on statistical methods, analyses of data and interpretation of such analyses, including figures, tables and text for statistical research conducted under EP-C-05-030, EP-W-09-024 and EP-W-16-017 (the current contract). Authorship decisions shall be based on the CPHEA authorship guidelines. Manuscripts that are expected to be either completed or prepared over the course of Option Period 4 Work Assignment 4-07 are as follows:

- Manuscript titled “Stability in Chemical Composition of Complex Mixtures of Disinfection By-Products”. This manuscript has undergone two rounds of review by the principal authors and is expected to need minimal effort by Battelle before review by all co-authors. The questions and comments received at the co-author, EPA internal, EPA clearance and journal review that focus on the statistical methodology and analysis, will determine the level of effort needed.
- A manuscript describing the results of the dose additivity assessment of the six possible binary combinations of the four regulated trihalomethanes. The manuscript will be prepared by EPA, with the methods section that describes the statistical analysis methods and the results section drawing substantially and heavily from reports previously prepared by Battelle under WA 3-07.
- A manuscript describing the results of the Expected Component Analyses of seven HAA mixtures in the CHO assay, including the underlying dose additivity evaluations conducted that were completed earlier by Battelle. The manuscript will be prepared by EPA, with the methods section that describes the statistical analysis methods and the results section drawing substantially and heavily from reports previously prepared by Battelle under WA 3-07 and EP-W-09-024.

Task 4. Determine Consistency with Dose Addition and Estimate the Contribution(s) of Individual Chemicals and Chemical Groups to the Toxicity of a Chemical Mixture

Task 4 is the centerpiece of Option Period 4 WA 4-07. In this task, the Contractor shall provide expert consultation with regard to mixtures analyses and, as directed, conduct statistical analyses to evaluate consistency with dose addition and estimate the contribution(s) of individual chemicals and chemical groups to the toxicity of a chemical mixture. These expert judgements and analyses shall be conducted using data and reports furnished by the U.S. EPA. The Contractor shall also provide expert consultation that provides insights into the interpretation of the results of statistical analyses of mixtures data. Common Elements in Task 4 are:

Review of Background Documentation: The Contractor shall review relevant background documentation and materials relevant to this Work Assignment. The EPA will provide reports, publications and draft manuscripts to the contractor. Additionally, the EPA will serve as a resource for relevant literature and background materials relevant to completion of the tasks.

Attend Teleconferences: The contractor shall participate in teleconferences to address any questions regarding the scope and goals of Tasks 3 and 4 and discuss the data, analytic requirements, relevant background information and available literature. A kick-off teleconference shall be conducted specific to each phase of Tasks 3 and 4. Additionally, the EPA and the Contractor shall have conference calls as needed to discuss and clarify technical issues related to the performance of each task. The EPA shall prepare summary notes which clearly summarize the teleconferences within five business days of each call.

Assess Data Quality: The Contractor shall assess databases to evaluate their data quality and integrity. The Contractor shall identify outliers and questionable data by reviewing data listings and summaries, applying statistical methods, and using graphical methods. The Contractor also shall review the data for missing values, censoring patterns, and appropriate units of measure (e.g., milligrams/liter). The Contractor shall conduct statistical analyses to assess consistency with or violations of assumptions underlying the proposed analyses (e.g., tests of homogeneity of variance). Prior to use of the data, the contractor shall identify the specific source of the data and also supply EPA with summary data for each dose group proposed for inclusion in the analysis, including the dose level, n, mean and standard deviation and identify any issues with the data such as heterogeneity and proposed transformations.

Develop computer programs: The Contractor shall ensure that all databases, computer programs, and the corresponding documentation developed under this contract are accessible to the EPA WACOR, and persons authorized by them. The Contractor shall provide this computer programming to technically support the statistical analysis specified in other areas of this performance work statement. All computer programs shall be well documented internally to facilitate EPA's review. Furthermore, the contractor shall use SAS for statistical analysis. At time intervals determined either by the status of the work (e.g. completion of an analysis or final acceptance by a journal of the article describing the analysis) or by the end of Option Period 4, the contractor shall provide all relevant computer programs to EPA.

Documentation: The Contractor shall internally document all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code so that results can be replicated even if the originating staff members are no longer available. The contractor shall provide access to this internal documentation upon request by the EPA WACOR. This documentation shall provide the foundation of the documentation of the products to be provided to EPA. The contractor shall provide documentation for products (i.e. analyses) in Task 4. The contractor shall provide documentation in computer files, and in hardcopy, upon specific request. The contractor shall incorporate EPA comments into revisions of the draft documentation. In all cases, description of the statistical methods and algorithms and the data used to generate results shall be provided electronically as well as in the appendix of the draft reports. Upon EPA review and acceptance of the results and reports, the documentation provided to EPA shall be expanded to include all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code used in accomplishment of the work effort as well as the SAS files themselves.

In any documentation, the contractor shall clearly specify the methods, procedures, considerations,

assumptions, relevant citations, data sources, and data that support the results and any recommendations. The contractor also shall document alternative methods, procedures, and assumptions that the contractor considered in the statistical analysis. Further, the documentation shall be labeled with the name of the contractor, the EPA contract number (EPW16017) and the work assignment number (4-07).

4.A. Statistical Analysis of Haloacetic Acid (HAA) Mixture Data Collected in Chinese Hamster Ovary Cells.

The analyses requested under Task 4A will be primarily completed or completed by the end of WA 3-07. The work will resume where work ended in WA 3-07. The primary effort anticipated with Task 4.A. under WA 4-07 will be based on any issues or questions identified during writing and peer-review of the manuscript.

4.B. Statistical Analysis of THM mixture data collected in Mice

Task 4.B effort examines selected aspects of the modeling work on THM mixtures in mice done under EP-C-05-030 and WA3-07. This effort included re-runs of the SAS programs whose results are the subject of the earlier reports. There were two main parts to this work: 1.) homogeneity of variances; and 2.) Lambda, smooth additivity model (SAM) and threshold additivity model (TAM). This work is expected to be primarily completed under WA 3-07 and will resume at the point where the work ended in WA 3-07.

- Homogeneity of Variances. Looking at the results of the previous analyses, an outstanding question is whether the variability in the response data is sufficiently high to create issues due to non-homogeneity of variances. The contractor shall:
 - Conduct statistical tests for homogeneity of variance for all binary data sets. These results will be used in consultation with and concurrence from EPA regarding whether transformation of the response data is appropriate.
 - If the decision is to transform, log10 is suggested, followed by another round of testing for homogeneity of variances.
 - It is suggested that this be done in advance of the lambda, smooth additivity and threshold additivity modeling based on the idea that the homogeneity of variance testing does not require identification of lambda and this order will save time and effort.
- Outliers. The contractor shall examine the data sets that have been provided by EPA for outliers.
 - Prior to the conduct of these analyses, propose the test(s) to be used and select the test(s) in consultation with EPA.
 - Conduct analyses to examine the presence of outliers.
 - In those cases where an outlier is identified, the results will be used by the contractor in consultation with and concurrence by EPA to decide if a 're-do' of the analysis is warranted for that binary combination and endpoint to determine where removal of the outlier value affects the result of the statistical analyses.

4.C. Statistical Analysis of HAA Mixture Data Collected in Whole Embryo Cultures

Task 4.C is a continuation of work under Option Period 3 WA 3-07 and work will resume in Option Period 4-07. The toxicity assay is a whole embryo culture assay. There are six endpoints of interest from the whole embryo cell culture assay: normal; dysmorphic, cranial NT, arch 1, heart, final somites. Based on the results of the Normal endpoint, two more endpoints may be analyzed; and, based on the analysis decisions made in 4.B. (Modeling of THM Binary Mixtures), up to three more endpoints may be evaluated.

Three mixtures were tested. The three mixtures are related in that each is a mixture of up to nine haloacetic acids (HAAs). The nine haloacetic acids are: chloroacetic acid, dichloroacetic acid, trichloroacetic acid, bromoacetic acid, dibromoacetic acid, tribromoacetic acid, bromochloroacetic acid, bromodichloroacetic acid and dibromochloroacetic acid. There are concentration response curves for each of these individual haloacetic acids. Mixture LBM is the mixture of these nine haloacetic acids representative of the mixing ratio (the relative proportions) in low bromide source water disinfected by chlorination. The LBM mixture contains only 7 of the 9 HAAs, as two of them were not detected under low bromide conditions (the 2 that are absent are bromoacetic acid and dibromoacetic acid). Mixture MBM is the mixture of these nine haloacetic acids representative of the mixing ratio (the relative proportions) of the 9 that are present in medium bromide source water disinfected by chlorination. The MBM mixture contains all 9 of the HAAs. Mixture HBM is the mixture of these nine haloacetic acids representative of the mixing ratio (the relative proportions) of the 9 that are present in high bromide source water disinfected by chlorination. The HBM mixture contains 8 of the 9 HAAs as one of them was not detected under high bromide conditions (the one that was not detected was chloroacetic acid). The mixing ratios of the three mixtures (LBM, MBM and HBM) are different, so each one is a unique ray, both in the number of HAAs contained in the mixture (7,8,9 for LBM, HBM and MBM, respectively) and in the proportions of the HAAs relative to one another. There are concentration response curves for each of the three mixture rays (LBM, MBM, HBM).

- The portion of this total effort that focused on the dose addition and expected component contribution score methodology (described in Hertzberg et al 2013, *Toxicology*, 2013, 313:134-144) were substantially completed in WA3-07. Work to complete this portion will resume in WA4-07 where work ended in WA3-07.

Work to be initiated and completed in WA4-07 include:

- determination of whether predictions of mixture effect, made under dose addition assumptions and models or predictions of mixture toxicity made under independent action assumptions or models or predictions of mixture toxicity made using integrated addition methods (see for example Rider et al, 2008, *Int J Androl.* 31(2):249-62) more closely approximate the observed mixture response.
- Performance of an analysis based on methodology for dose addition similar to that described in detail by Altenburger et al., 2000 (*Environ Toxicology Chemistry*, 19(9): 2341–2347) where the ‘best fitting model’ of each chemical and mixture is used in the analysis.

4.D. Modeling and Evaluation of 9 HAA Mixture Data collected in a Stem Cell Assay

Task 4.D. will examine the effect of the same mixtures described under the 4.C (the LBM, MBM and HBM) HAA mixtures in a different toxicity assay. The toxicity assay is a mouse embryonic stem cell adherent cell differentiation and cytotoxicity assay. There are two endpoints in the assays: reduction in cell number; and, effects on differentiation. The requested structure of this effort is the same as in Task 4.C. Specifically, to analyze these two endpoints for dose addition and to calculate the expected component contribution score based on the methodologies described in Hertzberg et al (2013). Following this, the contractor shall determine, whether predictions of mixture effect, made under dose addition assumptions and models or predictions of mixture toxicity made under independent action assumptions or models or predictions of mixture toxicity made using integrated addition methods (see for example Rider et al, 2008, *Int J Androl.* 31(2):249-62) more closely approximate the observed mixture response. The contractor shall also consider an analysis methodology similar to that described in detail by Altenburger et al., 2000 (*Environ Toxicology Chemistry*, 19(9): 2341–2347) where the ‘best fitting model’ of each chemical and mixture is used in the analysis.

SCHEDULE AND DELIVERABLES

Task No.	Deliverable Title/Brief Description	Due Date
1.A	Draft QAPP submitted to the EPA WACOR.	2 Week after Award
1.B	A final QAPP submitted to the EPA WACOR for approval.	2 Week after receiving comments on Draft QAPP.
2.	Technical and Financial Work Plan	30 days after Award
3.	Responses to EPA and/or journal reviewer comments; Contribution to new manuscripts	As specified in technical direction (or otherwise negotiated) as manuscripts are reviewed internally and by peer-review journals; responses due within 2 working weeks of receipt by the contractor, unless additional analyses are necessary
4.A	Report on statistical analysis from modeling HAA mixture data collected in Chinese hamster ovary cells	As specified in technical direction (or otherwise negotiated)
4.B	Report on statistical analysis of THM mixture data collected in mice	As specified in technical direction (or otherwise negotiated)
4.C	Report on statistical analysis of HAA mixture data collected in whole embryo cultures	As specified in technical direction (or otherwise negotiated)
4.D	Report on statistical analysis from modeling and evaluation of 9 HAA mixture data collected in a stem cell assay	As specified in technical direction (or otherwise negotiated)

The contractor shall provide written notification to the WACOR when 75 percent of the hours and/or funds have been spent on this work assignment. The contractor also shall immediately contact the EPA WACOR to discuss any problems that may adversely affect the work on this work assignment.

WORK ASSIGNMENT CONTRACTING OFFICER REPRESENTATIVE

Tony McDonald
Inhalation Toxicology Facilities Branch
Public Health and Integrated Toxicology Division
Center for Public Health and Environmental Assessment (CPHEA)
U.S. Environmental Protection Agency
MD B105-02, 109 T. W. Alexander Drive
Research Triangle Park, NC 27711

Attachment 1.

Template QAPP for existing EPA Animal Data for Statistical Modeling

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number WA4-10				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2021 Base Option Period Number 4			Title of Work Assignment/SF Site Name New Chemical Program Support				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2020 To 06/12/2021				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period: Cost/Fee: LOE: 06/13/2016 To 06/12/2021										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated: Cost/Fee LOE:										
Cumulative Approved: Cost/Fee LOE:										
Work Assignment Manager Name Monica Miller <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-6473 FAX Number:			
Project Officer Name Sheila Brown <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4651 FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name Erin M. Ridder <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 513-487-2155 FAX Number:			

PERFORMANCE WORK STATEMENT

Contract Number: EP-W-16-017

Work Assignment Number: 4-10

TITLE: New Chemical Program Support

PURPOSE:

This work shall be performed under Battelle Contract EP-W-16-017, Task III Technical Program Support- General Support. This work assignment provides support to the New Chemical Program (NCP) in processing of Pre- Manufacturer Notices (PMNs). No work performed under previous work assignments will be duplicated under this work assignment.

BACKGROUND:

This work assignment, entitled *New Chemicals Program Support*, is to provide EPA with support to expedite the processing of the Pre-Manufacturer Notices (PMNs) to reduce the backlog and provide support brought about by the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. This law became effective immediately upon being signed on June 22, 2016. The activities listed below will be an ongoing effort to: Provide PMN Status Tracking, Draft Letters and Consent Orders, Draft documentation needed for Significant New Use Rules (SNURs) and Statement on Administrator Finding to be published in the Federal register. Populate the Pre-Notice Communications Database, Provide Administrative Support to the New Chemicals Ad HOC Committee, and Provide Miscellaneous Administrative Support to the New Chemicals Program as the program changes to implement the new law.

EPA's New Chemicals Program is required to review and make an affirmative determination of risk on new chemical substances submitted for evaluation in premanufacture notices (PMNs) and significant new use notices (SNUNs) before manufacturing, processing and or use can commence. The review evaluates a new chemical substance given the information provided by the submitter of the PMN and the information readily available to EPA to determine if the new chemical substance poses a risk to human health or the environment. This review also includes an evaluation of physical and chemical characteristics of the substance, the fate, the human health and environmental hazards, exposures, and risk management to make the affirmative determination of risk. Once the determination is made EPA may regulate the manufacturing, processing and or use of a new chemical substance through a Consent Order and/or Significant New Use Rule (SNUR) which requires manufacturers/importers to alert EPA of any new uses of the new chemical substance. If the determination of not likely to present an unreasonable risk to human health or the environment is made, a notice of the determination must also be published in the Federal Register.

SCOPE OF WORK:

TASK 1. Work Plan and Monthly Progress Report

- A. The contractor shall submit a work plan to the Agency within fifteen (15) calendar days of receipt of the WA, in accordance with the Work Assignments clause in the base contract. The Contractor's work plan shall describe tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles.
- B. Provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA Technical Contact	Contractor lead staff	Topic	Hours		
					Allocated	Used this month	Cum used

Through technical direction, the WACOR will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

- C. Some work may require access to TSCA Confidential Business Information. The manager of this work assignment, as well as any staff working on reports that involve TSCA CBI, must be TSCA CBI cleared. They must also take supplementary CBI training designated by the EPA Contracting Officer Representative. Reports based on information drawn from TSCA CBI documents must be submitted to EPA as TSCA CBI, even if the contractor believes they have excluded CBI from the report. This is in addition to complying with all TSCA CBI requirements in the contract and in EPA's *TSCA CBI Protection Manual*.

TASK 2. Quality Assurance Project Plan (QAPP)

The contractor shall submit a Quality Assurance Project Plan (QAPP) in accordance with the Agency requirements for QAPP (QA/R-5). Detailed information may be found at www.epa.gov/quality. The contractor shall update the QAPP as needed (and in any case, at least once a year). For QAPP revisions, the contractor shall provide a list summarizing changes from the prior approved QAPP.

TASK 3. Document Sanitization

The contractor shall sanitize documents by removing Confidential Business Information (CBI) from Risk Assessment Division (RAD) Section 5 Risk Assessment documents. This will increasingly be asked for by companies as EPA eliminates the practice of sending Action Letters immediately drafting Consent Orders to be sent to PMN submitters upon finalization of the affirmative risk finding and development of risk management options.

TASK 4. Consent Order and SNUR Development

The Contractor shall provide support in developing draft TSCA section 5(e) Consent Orders and SNURs. After collecting documentation from the EPA Program Manager (PM) to include briefing papers, draft action letters, and other correspondence as well as data and information in PMN Gold and submitted PMNs, draft Consent Orders and SNURS. Drafts will be developed from boiler plates following instructions and using the information collected. After Draft is completed review with PM and prepare printed document for review and signature.

TASK 5. Miscellaneous Administrative Support

Provide miscellaneous support to the New Chemicals Program as needed, which may include preparation, scanning, shredding, uploading etc. of documents and file; database creation, population and maintenance; document control; completing information requests from management; and tracking progress of work effort to eliminate backlog of cases and information requests from Program Managers to the Risk Assessment Division.

TASK 6. Determination Support

Provide support, to make available to the public, all underlying documents supporting EPA's risk determinations. This support will include sanitization of the determination and related support

documents by removing Confidential Business Information (CBI); preparation of documents and language such as preambles and the statement of finding developed from boiler plates, following instructions and using the information in the determination and support documents; uploading documents into the appropriate public docket; and miscellaneous related support.

DELIVERABLES:

Task 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Task 2.	Quality Assurance Project Plan (QAPP) <ul style="list-style-type: none"> • Initial QAPP • Revised QAPP(s) 	<ul style="list-style-type: none"> • 10 days after WA issuance • Prior to work on environmental data activities
Task 3.	Document Sanitization	Within 7 days of request
Task 4.	Consent Order and SNUR Development	Within 14 days of request
Task 5.	Miscellaneous Administrative Support	Within 14 days of request
Task 6.	Determination Support	Within 14 days of request

- **A Quality Assurance Project Plan (QAPP) is necessary.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- **CBI does apply.**
- **Contractor personnel shall at all times identify themselves as contractor employees and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.**

PERIOD OF PERFORMANCE: June 12, 2020 through - June 13, 2021.

EPA CONTACTS:

Work Assignment Contracting Officer Representative

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Alternate Work Assignment Contracting Officer Representative

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 Phone: (202) 564-9138
Cool.Rebecca@epa.gov

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number WA4-14				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2021 Base Option Period Number 4			Title of Work Assignment/SF Site Name Alternative Testing Strategy;				
Contractor Battelle Memorial Institute					Specify Section and paragraph of Contract SOW Section I, Task 1-5					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 07/23/2020 To 06/12/2021				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:			LOE:					
06/13/2016 To 06/12/2021										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:					Cost/Fee		LOE:			
Cumulative Approved:					Cost/Fee		LOE:			
Work Assignment Manager Name Cory Strobe <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:			
							Phone Number: 202-564-4455			
							FAX Number:			
Project Officer Name Sheila Brown <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:			
							Phone Number: 202-564-4651			
							FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:			
							Phone Number:			
							FAX Number:			
Contracting Official Name Erin M. Ridder <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:			
							Phone Number: 513-487-2155			
							FAX Number:			

CONTRACT NUMBER: EP-W-16-017
WORK ASSIGNMENT NUMBER: 4-14

TITLE: EPA Office of Science Coordination and Policy; Office of Pollution Prevention and Toxics
Alternative Testing Strategy; Data Science; and Systematic Review Support

Work Assignment Contracting Officer Representative (WACOR)	Alternate Work Assignment Contracting Officer Representative (Alt WACOR)
Cory Strobe Office of Pollution Prevention and Toxics Risk Assessment Division Phone: (202) 564 4455 Email: strobe.cory@epa.gov	Joe Bever Office of Science Coordination and Policy Exposure Assessment Coordination & Policy Division Phone: (202) 564-8405 Email: bever.ronnie@epa.gov

PURPOSE:

This work assignment, *EPA Office of Science Coordination and Policy; the Office of Pollution Prevention and Toxics Alternative Testing Strategy; Data Science; and Systematic Review Support*, will provide technical support to EPAs Office of Chemical Safety & Pollution Prevention (OCSPP), including the Office of Science Coordination and Policy (OSCP) and the Office of Pollution Prevention and Toxics (OPPT). The technical support will address the Alternative Testing Strategy, performance-validation of high throughput (HT) assays, computational models for pathway-specific toxicity; and development and prioritization of chemicals. No work performed under previous task orders or work assignments will be duplicated under Work Assignment 4-14, EP-W-16-017. However, some of the work is a continuation of EP-W-16-017 Work Assignment 3-14.

BACKGROUND

This work assignment will provide technical support in three specific areas:

1. Task 3. Support the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; and
2. Task 4. Support OPPT systematic review for the development of risk evaluations.
3. Task 5. Support OCSPP development and application of new approach methods (NAMs) and the infrastructure to support such work.

The EPA regulates the manufacture, importation, use, and disposal of commercial chemical substances within the United States. The Toxic Substances Control Act (TSCA) of 1976 (U.S.C., 1976) provides the EPA with the authority to require reporting, record-keeping and testing requirements, and imposes restrictions relating to chemical substances and/or mixtures. The mandates under TSCA are carried out by the EPA Office of Pollution Prevention and Toxics (OPPT), which performs all evaluations on new and existing chemical substances. In 2016, TSCA was amended by the Frank R. Lautenberg Chemical Safety Act for the 21st Century (U.S.C., 2016) (hereinafter the “Lautenberg Act”). This amendment expanded EPA’s authority to include requirements on EPA to make affirmative risk determinations on new chemical substances prior to market entry, categorize existing chemical substances as low- or high-priority substances, and perform risk evaluations on high-priority substances to determine if they pose an unreasonable risk of injury to health or the environment. An additional legislative mandate that arose from the Lautenberg Act is the requirement for EPA to consider non-traditional data and to promote the development and implementation of New Approach Methods (NAMs). Specifically, the law calls for the

reduction and replacement, to the extent practicable and scientifically justified, of vertebrate animal use in toxicity testing. Section 4(h)(2)(A) provides some examples for consideration before EPA requests or requires toxicity testing: (i) computational toxicology and bioinformatics; (ii) high-throughput screening methods; (iii) testing of categories of chemical substances; (iv) tiered testing methods; (v) in vitro studies; (vi) systems biology; (vii) new or revised methods identified by validation bodies such as ICCVAM or the Organisation for Economic Co-operation (OECD), and (viii) industry consortia that develop similar information.

I. STATEMENT OF WORK

A. Task 1 Work Plan and Task Management

1. The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. The work plan will describe tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management activities.
2. Provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours Allocated	Hours used this month	Cumulative hours used

Through technical direction, the WACOR will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

3. Some work may require access to TSCA Confidential Business Information (CBI). The manager of this work assignment, as well as any staff working on reports that involve TSCA CBI, must be TSCA CBI cleared. They must also take supplementary CBI training designated by the EPA COR. Reports based on information drawn from TSCA CBI documents must be submitted to EPA as TSCA CBI, even if the contractor believes they have excluded CBI from the report. This is in addition to complying with all TSCA CBI requirements in the contract and in EPA's TSCA CBI Protection Manual.
4. The contractor shall immediately notify the EPA WACOR if there are any problems that affect the production and delivery of deliverables.
5. The contractor shall provide all deliverables in an electronic format specified by the EPA WACOR (e.g., Word, Excel, Access, HTML) via electronic mail. Unless otherwise specified by the EPA WACOR, Battelle shall provide a secure method for internet transfer of large files.
6. All Deliverables for WA 4-14 are the property of EPA (including any scripts or computer code developed accomplish analyses).
7. The contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

B. Task 2 Quality Assurance Project Plan (QAPP)

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 3, 4 and 5, in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at:

<https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf> and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

- C. **Task 3** Support the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. This Task fits specifically under the Contract SOW Task II. Data Analysis (II. 1 – 6).
1. **Data Processing on Existing Chemical Data.** The Contractor shall convert data from TSCA Sections 4, 5, 6, and 8 hazard, exposure, and fate databases not previously converted under WA 3-14 into a machine-readable format (such as ASCII). The contractor shall establish database links for the chemical, guideline, case number, and associated text as pertains to each record.
 2. **Data Analysis.** The Contractor shall continue to analyze which tests are most commonly requested, required, and available, and determine trends of data based on chemical classes and other variables as directed by EPA. This knowledge will be used to help optimize future testing strategy (data requests) and to determine tests that would most benefit from the development of alternative testing strategies.
 3. **Transformation of OPPT data to OECD Harmonized Templates.** The Contractor shall convert data from TSCA Sections 4, 5, 6, and 8 hazard, exposure, and fate databases into appropriate OECD Harmonized Templates based on Subtask 3.1 and shall upload this data into OPPT's IUCLID installation. As directed by EPA, the Contractor shall identify and implement approaches to extend the IUCLID system, integrate the system into other EPA systems, and develop workflows and interfaces in order to meet EPA's scientific and programmatic needs.
 4. **Chemical clustering.** The Contractor shall support the curation, clustering, and prioritization of chemical substances from the TSCA Inventory including analysis of substance nomenclature, chemical structure, and data on physical-chemical properties, use and exposures, and toxicology.
- D. **Task 4** Support OCSPP systematic literature reviews for the development of risk evaluations. This Task contains elements under both Task II. Data Analysis (II. 4 - 6) and Task III. Technical Program Support - General Support (III.1, 2, & 4).
1. **Data management of Systematic Reviews.** The Contractor shall support the development and implementation of systematic review templates (including the use of OECD Harmonized Templates, controlled vocabularies, etc.), reviewer workflows, and reference management in systematic review tools selected by EPA. Specifically, the contractor will identify processes and transitions between processes from systematic review protocol to develop an automated workflow for tracking systematic review progress and provide training to developers, assessors and other involved contractors. Development of a reference deduplication tool may also be part of this task
 2. **Systematic Review Analysis Tasks.** The Contractor shall support the data gathering (including data cleaning), tool validation, statistical analysis (such as meta-analysis of studies), visualization, toxicological review, and textual analysis (such as text mining and natural language processing analysis) related to systematic reviews; these tasks may also be applied to other data streams.
 3. **Building SOPs and workflows.** Write up of SOPs as needed.

- E. **Task 5.** Support OCSPP development and application of new approach methods (NAMs) and the infrastructure to support such work.
1. **Scientific Platform.** The Contractor shall install and maintain software on the TSCA CBI LAN in Linux and Windows environments in support of this project and for the TSCA NAM Team to support the overall implementation of the TSCA Alternative Testing Strategy. This includes, but is not limited to, R environments and packages, Python environments and packages, relational and non-relational databases (MySQL, PostgreSQL, MongoDB, etc.), internally facing web applications, etc.
 2. **Case Studies.** The Contractor shall support the development and execution of TSCA Alternative Testing Strategy case studies of mutual interest to OPPT and OSCP including analysis of chemical structure, in vivo, in vitro data, and exposure data
 - a. The application of the clustering results for refining chemical grouping in ECOSAR or the New Chemicals categories
 - b. The clustering validation may involve validation by chemical-assay screening via high throughput testing platforms

II. DELIVERABLES

- A. Table 1. Deliverables and Schedule
For tasks 3, 4 & 5, the Work Assignment COR's shall develop and provide specific technical direction to begin scoping the project. The deadlines are intended to be illustrative only for workplan development purposes; the table indicates when reports are to be delivered to the COR.

Task	Subtask	Deliverable	Projected Due Dates
Task 1. Work Plan and Task Management	1.1	The contractor shall prepare and submit the work plan in accordance with contract requirements.	In accordance with contract terms and conditions
Task 2. Quality Assurance Project Plan	2.1	1. Draft QAPP 2. Final QAPP	Draft: 10 days after WA start Final: Prior to work on environmental data activities
Task 3. Support the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act	3.1	1. Loading of OPPT data (toxicological, environmental fate, physical-chemical, exposure) into EPA enterprise (MySQL, Postgresql) systems (no report)	TBD through technical direction issuance from WACOR
	3.2	1. Naïve TSCA inventory clustering exploration using structures only and including both CBI and non-CBI information and analysis (report) 2. Combining the results from 3.2.1 above with available in vivo, in vitro, and other TSCA-relevant data (3.1) (report)	1. 8/15/2020 2. 10/30/2020

	3.3	<ol style="list-style-type: none"> 1. Pilot of <u>existing</u> EPA ecological toxicity data uploaded in the OPPT IUCLID instance (abbreviated report) 2. Development, implementation, and support of user workflows to support new extraction of ecological data directly in OPPT IUCLID instance (no report) 3. Further work and direction following steps 1 & 2 	<ol style="list-style-type: none"> 1. 9/30/2020 2. 12/30/2020 3. TBD through technical direction issuance from
	3.4	<ol style="list-style-type: none"> 1. Completion and analysis of <u>two</u> NAM templates as a case study of the proposed NAM nomination process (abbreviated report) 2. Analysis of literature search and data mining of relevant physical-chemical properties, in vitro, and in vivo for inhalation exposures to inform structural alerts not in the current lung effects category (including report) 3. Analysis and data mining (including report) of the ecological toxicity as it relates to ECOSAR categories (especially neutral organics) (including report) 4. Inhalation exposure decision-tree model from Deliverable #2 implemented in the QSAR toolbox profiler 5. Additional case studies at WACOR's request. 	<ol style="list-style-type: none"> 1. 9/15/2020 2. 12/15/2020 3. 6/1/2021 4. 3/15/2021 5. TBD through technical direction issuance from WACOR
Task 4. Support OCSPP systematic literature reviews for the development of risk evaluations	4.1	<ol style="list-style-type: none"> 1. Provide automated workflow in JIRA for systematic review process as outlined in the Systematic Review protocol with modification as directed by WACOR. 2. Training of automated workflow 3. Other deliverables issued via technical direction. 	<ol style="list-style-type: none"> 1. 3/15/21 2. Training Within two weeks of finalized automated workflow 3. Other deliverables TBD through technical direction issuance from WACOR

	4.2	<ol style="list-style-type: none"> 1. Manage projects within systematic review tools (such as DistillerSR, SwiftActiveScreener, HERO database, etc.), to include activities like assigning users to projects, updating workflow settings, creating and revising screening/evaluation/extraction forms, etc. 2. Manage and track data sources through the SR process, including activities such as deduplication of references, uploading references into various SR tools, and exporting screening information for use in data visualizations. 3. Provide support in creating data visualizations in tools (e.g. Tableau, HAWC) 4. Conduct validation reviews of SR results (e.g., screening determinations). Provide written report of the finding of any validation work. 5. Other deliverables at WACOR's request. 	1-5. TBD through technical direction issuance from WACOR
	4.3	<ol style="list-style-type: none"> 1. Develop new SOPs as directed by COR. Revise old SOPs to correspond to any changes in the SR process. This may include a roadmap with links to SOP pages. 	1. TBD through technical direction issuance from WACOR
	4.4	<ol style="list-style-type: none"> 1. Other deliverables required through technical direction 	1. TBD through technical direction issuance from WACOR
Task 5. NAMs	5.1	<ol style="list-style-type: none"> 1. Management of OPPT CBI LAN Linux and Windows Sandbox and Production Application Software 	1. Ongoing through WA; TBD through technical direction issuance from WACOR
	5.2	<ol style="list-style-type: none"> 1. Case study deliverables (APCRA and others) 	1. TBD through technical direction issuance from WACOR

1. EPA will approve the work plan within 30 days.
2. **A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
3. This work assignment involves the use of TSCA Confidential Business Information (CBI) for Task 3 and 5; otherwise, no CBI is involved.
4. Reports in MS Word will be submitted to the COR as identified in Table 1 for review. EPA will provide comments and may request revisions
5. Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent view of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including, but not limited to actual determination of EPA policy and

preparation of documents on EPA letterhead other than routine correspondences.

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number WA4-15			
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:			
Contract Number EP-W-16-017		Contract Period 06/13/2016 To 06/12/2021 Base Option Period Number 4		Title of Work Assignment/SF Site Name Fish Tissue Data Migration					
Contractor BATTELLE MEMORIAL INSTITUTE				Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2020 To 06/12/2021			
Comments:									
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div>									
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.									
SFO <input type="checkbox"/> (Max 2)									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars) (Cents)	Site/Project (Max 8)	Cost Org/Code
1									
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4									
5									
Authorized Work Assignment Ceiling									
Contract Period:		Cost/Fee:		LOE:					
06/13/2016 To 06/12/2021									
This Action:									
Total:									
Work Plan / Cost Estimate Approvals									
Contractor WP Dated:				Cost/Fee		LOE:			
Cumulative Approved:				Cost/Fee		LOE:			
Work Assignment Manager Name Samantha Fontenelle <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:			
						Phone Number: 202-566-2083			
						FAX Number:			
Project Officer Name Sheila Brown <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:			
						Phone Number: 202-564-4651			
						FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:			
						Phone Number:			
						FAX Number:			
Contracting Official Name Erin M. Ridder <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:			
						Phone Number: 513-487-2155			
						FAX Number:			

PERFORMANCE WORK STATEMENT
EP-W-16-017
WORK ASSIGNMENT 4-15

TITLE: Fish Tissue Data Migration

BACKGROUND:

Since 1998, EPA's Office of Science and Technology has been collaborating with EPA programs and other partners to conduct a series of freshwater fish contamination studies. These studies provide nationally representative data on concentrations of a large number of chemicals in fish tissue to support critical Agency missions related to water and air quality. These data are also collected to provide state, local, regional and tribal environmental health officials with relevant information to inform fish advisories and safe eating guidelines.

SCOPE OF WORK:

For this work assignment (WA), the Contractor shall assist EPA with data clean up and standardization, conversion of data in Excel tables to the WQX web Water Quality Exchange (WQX) XML format, and the import of data into the WQX.

TASKS:

A. TASK 1 – Work Plan and Monthly Progress Report

The contractor shall submit a work plan to the Agency within fifteen (15) calendar days of receipt of the WA. The contractor work plan shall describe tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles. The contractor shall provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours		
					Allocated	Used this month	Cum used

B. TASK 2 – Quality Assurance Project Plan (QAPP)

A Quality Assurance Project Plan (QAPP) has been approved by the Contractor's quality assurance/quality control (QA/QC) officer and the EPA/OST QA/QC officers under WA 1-15. The Contractor shall revise the QAPP to reflect the change in scope of this WA, key personnel or approach where applicable. All deliverables including the Monthly Progress Reports shall include a report describing compliance with the QAPP. The work performed in this PWS shall conform to the Information Quality Guidelines (IQG) Checklist (Attachment A). The completed checklist and final QAPP shall be submitted with the final deliverables.

C. TASK 3 – EPA Fish Tissue Data in WQX

The EPA data (OST_SHPD) dataset includes fish tissue data from three studies: GLHHFTS2010, NRSA0809 and NRSA 1314. The Contractor shall support EPA with addressing issues identified with this dataset. This support will also include data conversion/mapping to the WQX web XML format and import into WQX. The following EPA studies have been provided to the contractor to include in WQX:

- Great Lakes Human Health Fish Tissue Study 2010
- National Rivers and Stream Assessments 2008–09
- National Rivers and Stream Assessments 2013–14

EPA continues to collect data as part of the National Rivers and Streams Assessment and the National Coastal Condition Assessment. As additional data become available, they may be provided to be imported into WQX.

DELIVERABLES:

The Contractor shall prepare draft deliverable(s) for review by the EPA WACOR in accordance with the deliverable schedule in section IV or by technical direction (TD). In preparing final written deliverables, the Contractor shall incorporate written comments from the EPA WACOR and submit the final deliverables in accordance with the deliverable schedule in section IV or TD. The EPA WACOR will review and approve all final deliverables.

Draft and final deliverables of data, databases and maps shall be provided to the WACOR electronically. Electronic files shall be provided in PDF and/or in the original software (Excel, Word). The Contractor shall use Microsoft Office and Adobe Acrobat software for developing all electronic copies of deliverables associated with the work assignment.

SCHEDULE OF DELIVERABLES:

Task	Deliverable	Schedule
1	Work Plan	Per contract requirements
2	Revised QAPP	As necessary and/or as requested by the WACOR
2	Final QAPP	One month before work assignment completion
2	Information Quality Guidelines	Within 10 business days of completion of the work assignment
3	Status updates on EPA data revisions/changes and data files for review prior to upload into WQX	As requested by the WACOR

REPORTING:

The Contractor shall include all progress for this WA in the monthly report prepared for this contract. The monthly report shall also include a report describing compliance with the QAPP and any QA issues encountered and recommendations for resolution. Financial reports shall also be completed as specified in the contract. Financial reports shall also be completed as specified in the contract. The Contractor shall maintain a file of all documentation, including raw data, calculations, assumptions, telephone contacts, and sources of information. During the period of performance of this work, the contractor shall immediately inform the EPA WACOR by email of any problems that may impede performance along with any corrective actions needed to solve the problem.

CONTRACTOR IDENTIFICATION:

Contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, Contractor personnel shall wear a badge which identifies the individual as a contractor employee.

Contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

TRAVEL:

No travel is anticipated under this work assignment. However, any travel chargeable to this work assignment shall be allowable only in accordance with the limitation of FAR 31.205-43 and FAR 31.205-46 and must be approved by the EPA Project Officer prior to travel taking place.

PRINTING:

All copying and printing shall be accomplished within the limitations of the printing clause of the contract.

MEETINGS, CONFERENCES, TRAINING EVENTS, & RECEPTIONS:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, including the form 5170 for all meetings costing more than \$20,000, shall be obtained by the EPA CL COR as needed and provided to the Contracting Officer Work under conference-related activities and expenses shall not occur until this approval is obtained and provided by the EPA CL COR.

PERIOD OF PERFORMANCE: 6/13/2020 through 06/12/2021

EPA CONTACTS:

- A. Work Assignment Contracting Officer Representative (WACOR):
Samantha Fontenelle
Standards & Health Protection Division
US EPA (4305T)
1301 Constitution Ave NW
Washington, DC 20460
202-566-2083
Fontenelle.Samantha@epa.gov

- B. Alternate Work Assignment Contracting Officer Representative (Alt WACOR):
Lisa Larimer
Standards & Health Protection Division
US EPA (4305T)
1301 Constitution Ave NW
Washington, DC 20460
202-566-1017
Larimer.Lisa@epa.gov

ATTACHMENT A
Office of Water Information Quality Guidelines Checklist for Non-*Influential Information*

Office of Water
Information Quality Guidelines Checklist for
Non-Influential Information

- ☐ The information to be disseminated is covered under The Guidelines.
- ☐ The information is in compliance with EPA's Quality System and other related policies.
- ☐ The information is in compliance with Office of Water's Quality Management Plan.
- ☐ The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
- ☐ Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
- ☐ Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
- ☐ Utility: the information is useful to the intended users.
- ☐ Meets "transparency" quality standard: the public can understand the source of the information and how conclusions were reached on the information.

Division Director's Signature & Date

IQG Officer for OW Signature & Date

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number WA4-17				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2021 Base Option Period Number 4			Title of Work Assignment/SF Site Name Lake Superior and Lake Huron				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/15/2020 To 06/12/2021				
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Contract Period: Cost/Fee: LOE: 06/13/2016 To 06/12/2021										
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Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated: Cost/Fee LOE:										
Cumulative Approved: Cost/Fee LOE:										
Work Assignment Manager Name Elizabeth Laplante <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 312-353-2694 FAX Number:			
Project Officer Name Sheila Brown <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4651 FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name Erin M. Ridder <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 513-487-2155 FAX Number:			

PERFORMANCE WORK STATEMENT (PWS)
EP-W-16-017
WORK ASSIGNMENT 4-17

TITLE: Superior and Huron Lakewide Action and Management Planning

BACKGROUND:

Lakewide Management under Annex 2 of the GLWQA is led by USEPA in the United States (and Environment and Climate Change Canada (ECCC) in Canada). EPA and ECCC collaborate with U.S. and Canadian environmental and natural resource management agencies, referred to collectively as “the Lake Partnership”. The Lake Partnership has two levels: its Working Group and its Management Committee. There is a Lake Partnership for each of the five Lakes.

LAMPs assess environmental conditions on a whole-lake basis and identify restoration and protection priorities. LAMPs are developed for each Great Lake every five years, with the Lake Michigan LAMP scheduled for completion in 2019, Superior in 2020, Huron in 2021, Ontario in 2022 and Lake Erie in 2023.

In addition, the Great Lakes Water Quality Agreement calls for a “Coordinated Science and Monitoring Initiative” (CSMI) for each of the lakes, on a five-year rotating basis. The Lake Huron CSMI was reported out in October 2019 at the State of Lake Huron conference, and development of new science priorities is scheduled for 2020, with a workshop in 2020, in preparation for the next monitoring year of 2022.

The LAMP for Huron was completed circa 2018. This document is well-developed and supplies a robust foundation for an update. It was developed with contract support from Battelle Memorial Institute. The Huron LAMP will be updated during 2021-22. Funding for the Lake Superior LAMP production support is also included in this work assignment in the event that the public comment period takes longer than the scheduled completion date of December 2020.

In general, the writing style of the CSMI monitoring priorities, matrix and background paper will be concise and use the active voice. The writing will be in plain English to serve federal, state and tribal resource staff and managers. The contractor shall provide document production support, spreadsheets, background papers, and technical editing. The contractor shall help with formatting and editing of the Lake Huron LAMP as well as prepare a source inventory for critical Lake Superior pollutants. EPA’s WACOR will coordinate within the working group and track contributions from government employees.

SCOPE OF WORK:

This work assignment supports environmental planning related to Lakes Superior and Huron. The Contractor shall be responsible for the facilitation support of the Lake Huron CSMI workgroup and workshop and the development of CSMI supporting documents for the Lake Huron workgroup to include the following tasks:

- Lake Huron CSMI workgroup and workshop and supporting documents
- Workgroup and meeting support for Lake Superior and Lake Huron

- Lake Superior chemical source inventory
- Lake Huron LAMP editing/formatting and final completion of Lake Superior LAMP
- Annual reports for all five lakes

TASKS

A. Work plan and Monthly Progress Report:

The contractor shall submit a work plan to the Agency within fifteen (15) calendar days of receipt of the WA, in accordance with the Work Assignments clause in the base contract. The Contractor's work plan shall describe tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles. The contractor shall provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours		
					Allocated	Used this month	Cum. used

B. Support to planning CSMI activities:

Each of the Lakes has multiple jurisdictions that contribute to LAMP activities. Every 5th year, one activity is called CSMI, Coordinated Science and Monitoring Initiative. Annex 10 (under the GLWQA) co-chairs will lead the CSMI coordination process. This requires coordination between the US and Canada, and their many affiliated jurisdictions, about what chemical, biological, or terrestrial metrics to sample and analyze, in order to better inform understanding of conditions in the environment. Government stakeholders share the priorities with the public and invite suggestions and feedback.

The Contractor shall assist with the facilitation of the Lake Huron CSMI process including facilitation of the CSMI workgroup. The Contractor shall be responsible for facilitating the CSMI workshop, meetings, planning calls, webinars, and background/summary materials related to the workshop, and other documents necessary for the successful implementation of the CSMI process. The Contractor shall continue to coordinate webinars and meetings of the CSMI workgroup until the priorities are finalized and submitted to the Annex 10 co-chairs.

C. Support to lake workgroups:

The Contractor shall support lake-wide planning by workgroups addressing Lakes Superior and Huron. In general, there are two meetings per calendar year for each lake. Superior meetings are usually three days in duration, plus travel time on either end. Huron is usually two days. The Contractor shall attend two Lake Huron and two Lake Superior meetings during the contractor period. The contractor shall also attend conference calls leading up to these in person sessions. Support includes drafting action items, notes and minutes of meetings.

D. Lake Superior Chemical milestones source inventory, 2015-2020:

The contractor shall begin work on the source inventory for Lake Superior critical pollutants from the period 2015-2020. The source inventory report will be similar to the 2010 and 2015 Chemical source inventories. Specifically, the contractor shall develop the

outline for the source emissions and discharges of the Zero Discharge Demonstration critical pollutants.

E. Lake Huron LAMP /Finalization of Lake Superior LAMP:

The Contractor shall assist with the editing and formatting of the Lake Huron LAMP, based on inputs and comments from the Huron partnership, and based on the outlines from the most recent LAMPs, including Lake Superior and Michigan. The Contractor shall also be responsible for the final formatting and editing of Lake Superior LAMP in anticipation of final completion.

F. Lake Annual Reports:

The Contractor shall edit, format and finalize the five draft Lake annual reports using content and images provided by the respective Lake Partnerships. The format shall be based on outlines from prior years and a provided template, with input from the Annex 2 Co-Chairs.

G. Applicable Documents:

Lake Huron LAMP <https://www.epa.gov/sites/production/files/2018-04/documents/lake-huron-lamp-2017-2021-105pp.pdf> is the model for technical writing and LAMP development. As the Lake Superior LAMP is developed and finalized, updated formats approved by management may be used for the Lake Huron LAMP.

H. Places of Performance:

During 2020-2021, two in-person meetings will take place in Superior Watershed and two meetings in the watershed of Lake Huron, depending on the travel situations of each country.

SCHEDULE OF DELIVERABLES:

The contractor shall provide all documents in original source formatting, in addition to MS Word and PDF.

Task	Milestones	Format	Deliverables due
A.	Workplan and Monthly Progress Reports	Word document and *.PDF document emailed to Contract-Level COR <i>and</i> the Contracting Officer. Upload in FedConnect.	Proposed workplan due within 15 days of work assignment issuance. Monthly progress reports are due IAW Contract clause.
B	Facilitation support of the Lake Huron CSMI workgroup and workshop. Development of CSMI priority documents for Lake Huron workgroup.	Word document and *.PDF document emailed to COR. Upload in FedConnect.	Lake Huron draft workshop agenda with one month of CSMI workshop Fall 2020 (dependent on workshop date).
C	Support to workgroups including meetings of the Lake Superior and Lake Huron workgroups	Word document and *.PDF document emailed to COR. Upload in FedConnect.	Attend two in-person meetings each for Superior and Huron and provide minutes to memorialize decisions and action items

D	Preparation of source inventory for Lake Superior critical pollutants	Word document and *.PDF document emailed to COR. Upload in FedConnect.	Initial assessment of source inventory data from 2016-2020
E	Huron LAMP formatting/editing and finalization of Lake Superior LAMP	Word document and *.PDF document emailed to COR. Upload in FedConnect.	2 nd draft LH LAMP formatting 20 days after EPA inputs (circa February 2021). 3 rd draft May 2021 Finalization of LS LAMP June 2021
F.	Lake Annual Reports	Word document and *.PDF document emailed to COR. Upload in FedConnect.	1 st draft outlines of all annual reports due June 2021

PERIOD OF PERFORMANCE: Work Assignment issuance through June 12, 2021.

US EPA POINTS OF CONTACT:

U.S. Environmental Protection Agency, Region 5, Great Lakes National Program Office

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